IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Hisashi Narimatsu, Takashi Kudo and Hiroko Iwasaki		
Application No.:	10/509,785	Group:	1652
Filed:	May 11, 2005 (371(c))	Examiner:	Iqbal H. Chowdhury, Ph.D.
Confirmation No.:	3100		
For:	NOVEL GALACTOSYLTRANSFERASES, THEIR PEPTIDES, AND NUCLEIC ACIDS ENCODING THE SAME (as amended)		

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REPLY TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Responsive to the Restriction Requirement dated October 18, 2005, the claims of Group II (Claims 5-7 and 9) drawn to an isolated polypeptide galactose transferase and invention (A) drawn to a protein of SEQ ID NO: 2 or a nucleic acid encoding SEQ ID NO: 2 are elected for prosecution. Applicants reserve the right to file a continuing application or take such other appropriate action as deemed necessary to protect the non-elected inventions. Applicants do not hereby abandon or waive any rights in the non-elected inventions.

The requirement is being traversed for the reasons set forth in detail below.

An extension of time to respond to the Restriction Requirement is respectfully requested. A Petition for an Extension of Time and the appropriate fee are being filed concurrently.

The Examiner states that the inventions listed as Groups I-X in the Office Action do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Specifically, the Examiner states that the polynucleotide encoding the polypeptide galactose transferase of Group I, polypeptide galactose transferase of Group II and antibody of Group III, pharmaceutical of Group IV, drug of Group VIII and genetically altered animal of Group X are each unrelated and chemically distinct entities. The Examiner acknowledges that the shared technical feature of Groups I-IV, VIII and X is that "they all relate to a polynucleotide encoding a polypeptide galactose transferase." (See Office Action at page 4, lines 4-5). However, the Examiner states that this shared technical feature is not a "special technical feature" as defined by PCT Rule 13.2, as it does not define a contribution over the prior art, namely, over a DNA encoding a galactose transferase known in the art as disclosed by Ju *et al.* "*Cloning and Expression of Human Core 1β1, 3-galactosyltransferase, J. Biol. Chem.*, January 2002, 277(1):178-186 (hereinafter "Ju *et al.*" (Reference C20 of record)).

Please note that Group X is directed to a method of screening a compound by using the transgenic animal recited in the claims of Group IX. Applicants request that the Examiner clarify whether the "Group X" recited in the aforementioned statement has been correctly identified. For the purposes of replying to the restriction requirement, Applicants will assume that the Examiner meant "Group IX", drawn to a genetically altered non-human animal, and respond accordingly.

In order to qualify as a special technical feature(s), the claimed feature(s) must distinguish over the prior art. Special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. MPEP Eighth Eds., Rev. 3, August 2005 at 1800-201, col. 1, paragraph 1. Thus, if there is a special technical feature(s) shared by certain claims that is distinct from the prior art, then unity of invention exists among the claims linked by such a feature. In the present case, the galactosyltransferases disclosed by Applicants are distinct from the galactose transferase

disclosed in Ju *et al.* For example, it is shown in FIG. 2 of the instant application that the enzyme C1Gal-T1 disclosed in Ju *et al.* and the enzyme C1Gal-T2 (SEQ ID NO: 2) claimed by Applicants share only 25.6% amino acid sequence identity. Further, it is clear that the genes that encode C1Gal-T1 and C1Gal-T2 (SEQ ID NO: 1) are also distinct as the C1Gal-T1 gene taught by Ju *et al.* is located at 7p14 and the C1Gal-T2 gene of Applicants' invention is located at Xq24; these are completely different loci on completely different chromosomes.

Similarly, the galactosyltransferase enzyme C1Gal-T3 claimed by Applicants is distinct from the C1Gal-T1 enzyme disclosed in Ju *et al.* The C1Gal-T3 gene (SEQ ID NO: 18) is located at 2p22, a different locus than that of C1Gal-T1 (i.e., 7p14). Moreover, FIG. 10 illustrates that the amino acid sequence of C1Gal-T3 (SEQ ID NO: 19) shares 68% amino acid sequence identity with the C1Gal-T2 enzyme (SEQ ID NO: 2) of Applicants' invention, demonstrating that the C1Gal-T3 amino acid sequence is also distinct from C1Gal-T1.

In the Preliminary Amendment filed concurrently herewith, Claim 1 has been amended to recite a polynucleotide encoding a polypeptide or a polypeptide comprising an amino acid sequence having at least 40% identity to the amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 19, which further distinguishes the polynucleotides and polypeptides of Applicants' claimed invention (i.e., C1Gal-T2 and C1Gal-T3) from those disclosed by Ju *et al.* (i.e., C1Gal-T1). Thus, Ju *et al.* does not disclose or teach the C1Gal-T2 or C1Gal-T3 gene or gene product of Applicants' claimed invention (i.e., a polynucleotide encoding a polypeptide or a polypeptide comprising an amino acid sequence having at least 40% identity to the amino acid sequence of SEQ ID NO: 2 or 19) and, therefore, Applicants' claimed invention is distinguished from that which is disclosed in Ju *et al.*

Accordingly, Groups I-IV, VIII and IX share a technical feature (as stated by the Examiner in the Office Action at page 4, lines 4-5) that is a "special technical feature" under PCT Rule 13.2, as the shared technical feature defines a contribution over the prior art. As such, Groups I-IV, VIII and IX are linked so as to form a single general inventive concept under PCT Rule 13.1

and, consequently, should be examined as a single group. Reconsideration and withdrawal of the requirement for restriction are requested.

Respectfully submitted,

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